

## STERYFLON Plus 1440 MINI FILTERS

- Intrinsically Hydrophobic PTFE membrane
- High permeability versus gas
- Repeatedly steamable in situ or in autoclave
- Thermowelded construction
- FDA-listed materials per CFR21
- Bio-Safety per USP-Plastics
- Validation Guide available on request



STERYFLON Plus 1440 mini filters are an important extension of PTFE membrane filter line. These mini filters are specifically designed for sterile filtration of compressed air and gas in pharmaceutical, bioengineering and food & beverage applications, and also for filtering high purity solvents in microelectronics. The filter media is a hydrophobic expanded PTFE with liquid absolute filtration rating of 0.1 and 0.2 micron, pleated with upstream and downstream support layers in nonwoven polypropylene. STERYFLON Plus 1440 mini filters are manufactured in a controlled environment and each filter is integrity tested and validated for bacterial retention correlated with microbiological challenge test.

### MATERIALS OF CONSTRUCTION

<b>Filter media</b>	PTFE hydrophobic membrane
<b>Upstream supports</b>	polypropylene
<b>Downstream supports</b>	polypropylene
<b>Internal Core</b>	polypropylene
<b>External Cage</b>	polypropylene
<b>End caps/Adapters</b>	polypropylene

### BIO-SAFETY

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics. The filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml).

### QUALITY STANDARDS

Produced under a certified Quality System to guarantee traceability of manufacturing records and integrity testing results.

### OPERATING CONDITIONS

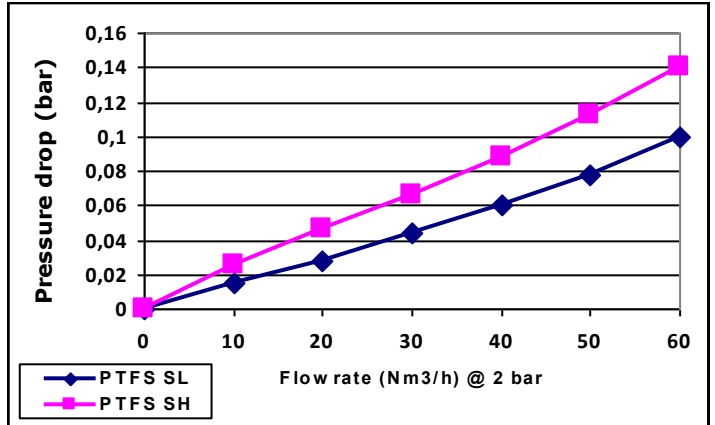
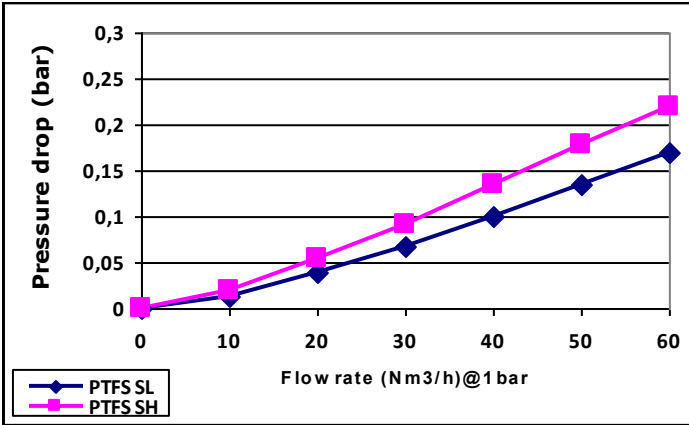
- max. continuous temperature in air	65 °C
- max. cumulative time of steam sterilization	100 hours at 125 °C with cycles of 60 minutes
- sanitization with chemicals	can be sanitized by standard chemical agents
- max. differential pressure	5,0 bar at 25 °C
- recommended change out differential pressure	2,0 bar at 25 °C

CODE	ABSOLUTE FILTRATION RATING		3) BACTERIAL RETENTION >10 <sup>7</sup> CFU/cm <sup>2</sup>	ACCEPTABLE LIMIT FOR INTEGRITY TEST
	IN LIQUID	IN DRY GAS		
SH	0,1 µm	< 0,01 µm	Acheleoplasma laidlawii in liquid	1) ≤ 13 ml/min @ 1,0 bar
SL	0,2 µm	< 0,01 µm	Batteriofago T1 in aerosol	1) ≤ 6 ml/min @ 0,8 bar
SLA	0,2 µm	< 0,01 µm	Brevundimonas diminuta in liquid	2) ≤ 8 Nml/10min @ 2,5 bar

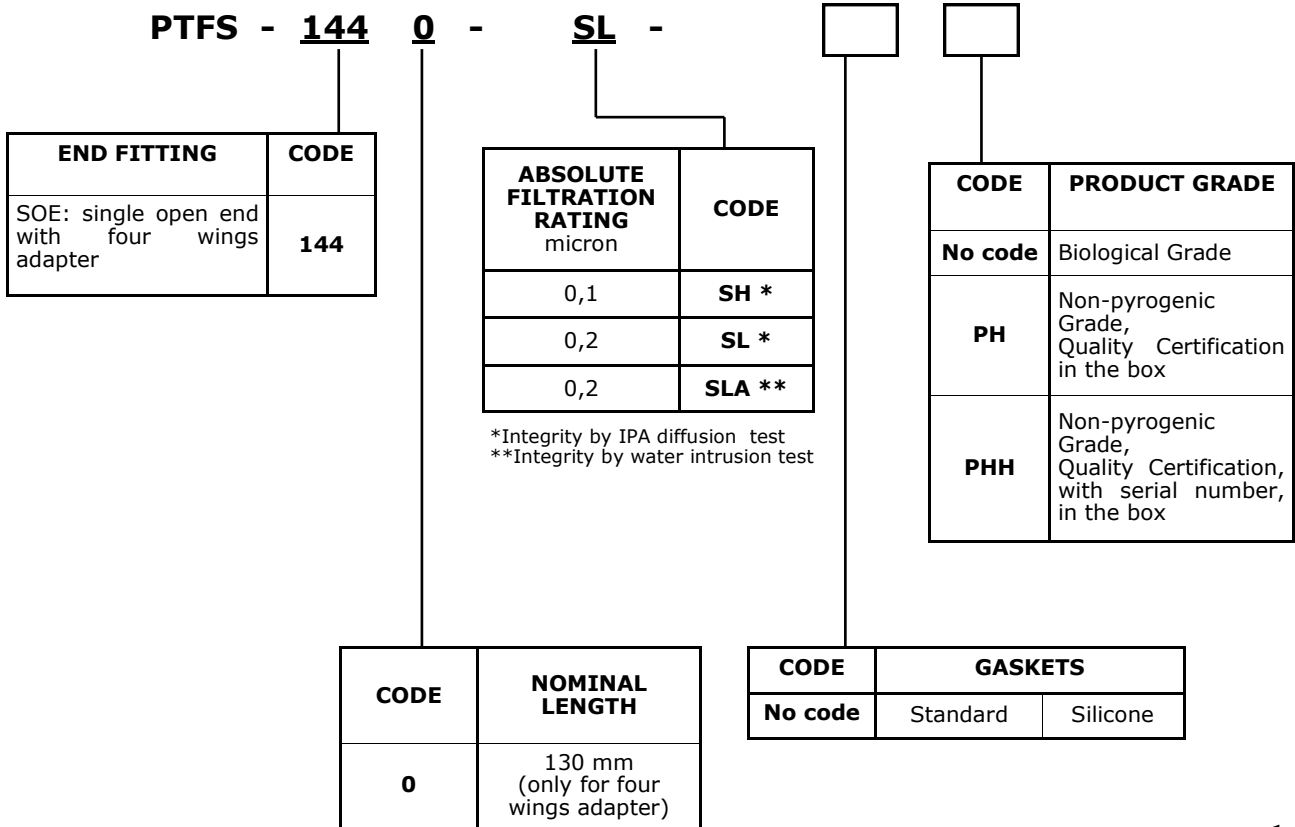
Note:

- 1- The integrity is verified by DIFFUSION TEST using an aqueous solution of isopropyl alcohol (IPA 60/40 V/V) as wetting liquid.
- 2- The integrity is verified by WATER FLOW INTRUSION TEST.
- 3- Mini filters are validated for retention of the microorganism reported in the table according to ASTM F838

## AIR FLOW RATE CURVES



## STERYFLON Plus 1440 MINI FILTERS ORDERING INFORMATION



Data contained in this bulletin are informative and subject to change without notice. User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.

DS-PTFS 1001-561bis-EN-23/A



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